

Remarks

I. Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-4 and 6-7 are pending in the application, with claim 1 being the independent claim. Claim 5 is cancelled. Support for the amendments to the claims may be found throughout the specification as originally filed, either inherently or explicitly. Specifically, support for the amendment to claim 1 can be found in the specification at page 11, lines 16-28, page 14, lines 5-21, Example 6, page 27, lines 28-30. Support for the amendment to claims 2-3 and 6-7 can be found at page 11, lines 27-28, page 14, lines 5-7, page 27, lines 28-30. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and that they be withdrawn.

II. The Rejections under 35 U.S.C. § 112, First Paragraph Are Traversed

In section 3 of the Office Action at pages 2-5, claims 1-7 were rejected under 35 U.S.C. § 112, first paragraph for allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and use the invention. Applicants respectfully traverse this rejection.

With regard to the Veronese reference, the Office Action states that the reference "does indicate that CTL responses may be useful in the control of viral spread and infection. However, the Veronese reference indicates that these responses are HIV-1 specific and provides no information as to whether such responses to self-antigens would

be so useful" Office Action at page 4. Veronese teaches that HIV infection upregulates the synthesis of the endogenous host protein, vinculin, which in turn causes the "priming of autoreactive vinculin-specific CTL responses." *See* Veronese at page 2515. The point of the reference was "[t]he identification of naturally processed, class I-presented peptides unique to HIV-infected cells," whether these peptides are viral or endogenous. *See* Veronese at page 2509. Hence, this reference confirms the plausibility of potential vaccine targets for infectious diseases which are based on differentially expressed self-peptides.

In making the rejection, the Office Action contends that "the Declaration is not commensurate in scope with the claims" because "the claims are not limited to proteins that are expressed on the cell, but to any protein that is upregulated, including secreted proteins." Office Action at page 4-5. Applicants respectfully disagree with this rejection. However, to expedite prosecution of the present application, and not in acquiescence to this rejection, claim 1 has been amended to recite "screening said human gene products for a cytotoxic T lymphocyte (CTL) response in humans."

As disclosed in the present specification, cellular peptides derived by degradation of endogenously synthesized proteins bind to class I MHC molecules for transport to the cell surface. These class I MHC:peptide complexes are the target antigens for specific CD8+ cytotoxic T cells. *See* specification at page 14, lines 8-11. Hence, in order for the peptides to be recognized by the cytotoxic T-cells, the peptides must be presented on the MHC molecule and not as secreted proteins. Therefore, since the claims now require that the peptides be recognized by cytotoxic T lymphocytes, and in order to be recognized the peptides must be expressed on cell surfaces as part of an MHC complex, the claims are commensurate in scope with the Declaration of Dr. Donald F. Hunt ("the

Hunt Declaration") and one of ordinary skill in the art would be capable of making and using the invention.

Given the present amendments, the Veronese reference and the Hunt Declaration which shows analogy between the art of anti-tumor vaccination and the present invention, one of ordinary skill in the art would be able to make and use the invention as claimed. Thus, the Applicant believes that the present claims are fully enabled and meet all the requirements of 35 U.S.C. § 112, first paragraph. Accordingly, reconsideration and withdrawal are respectfully requested.

In section 4 of the Office Action at pages 5-7, claims 1-7 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and use the invention. Applicants respectfully traverse this rejection.

The Office action stated that "if the claimed method were found to be enabled it would be for embodiments where the up-regulated self-antigen is capable of inducing an immune response in the host organism." Office Action at page 6. To expedite prosecution of the present application, and not in acquiescence to this rejection, claim 1 has been amended to specify that the upregulated self-antigen is capable of inducing an immune response in the host organism, i.e., humans. Accordingly, this portion of the rejection has been accommodated. Reconsideration and withdrawal are respectfully requested.

VI. Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the

Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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